

35 U.S.C. § 112, first paragraph
and the Wands Analysis

Removal of SPE 1036

(571) 272-0781

35 U.S.C. § 112, first paragraph and the Wands Analysis

Rem 15-36

35 U.S.C. § 112, first paragraph enablement

- "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

35 U.S.C. § 112, first paragraph enablement

- "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."
 - United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)
- A patent need not teach, and preferably omit, what is well known in the art.

MPEP § 2164.05

- "In making the determination of enablement, the examiner shall consider the original disclosure and all evidence in the record, weighing evidence that supports enablement against evidence that the specification is not enabling."

Test for Enablement

- Determine of scope of the claimed invention
- Ascertain if the teachings in the specification are commensurate in scope such that one of skill in the art could practice the invention (over its full scope) without undue experimentation

Test for Enablement

- If the statement of utility contains within it a connotation of how to use, and the art recognizes that standard modes of administration are contemplated, 35 U.S.C. is satisfied.
-MPEP 2164.01 (c)

For Example

- If one skilled in the art could obtain such information without undue experimentation, then it is not necessary to specify the dosage or method of use.
- If one of ordinary skill would be able to discern an appropriate dosage or method of use based on knowledge of compounds having similar physiological or biological activity without undue experimentation, this will be sufficient to satisfy 35 U.S.C. 112.

If on the other hand....

- The use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied in the disclosure.
- The information regarding dosage or method of making and using cannot readily be discerned from the prior art and the disclosure, then an inquiry into the level of experimentation necessary to ascertain this information is appropriate.

Standard for Enablement

- The standard for determining whether the specification meets the enablement requirement:
 - Is the experimentation needed to practice the invention undue or unreasonable?
 - Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916)
 - M.P.E.P. 2164.01

Undue Experimentation

- The test of enablement is not whether any experimentation is necessary, but whether if experimentation is necessary, it is undue.
 - (*In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (CCPA 1976))

Undue Experimentation

- There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."
 - M.P.E.P. 2164.01

In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)

- The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination.

Wands Factors

- the nature of the invention
- the state of the prior art
- the predictability or lack thereof in the art
- the amount of direction or guidance present
- the presence or absence of working examples
- the breadth of the claims
- the relative skill of those in the art
- the quantity of experimentation needed

Undue Experimentation and Enablement

- It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others.
- The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

Undue Experimentation and Enablement

- A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

— In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Wands Factors

- Provide a framework for analyzing the level of experimentation required of one of skill in the art
- Not all factors are relevant for every enablement determination
- Wands Factor format used in *Enzo Biochem Inc. v. Calgene Inc.* (CAFC) 52 USPQ2d 1129 has been adopted by the Board of Patent Appeals and Interferences

Predictability and state of the art and the Enablement Requirement

- The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art.

- The "amount of guidance or direction" refers to information in the application, as originally filed, that teaches exactly how to make or use the invention.

- In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CC 1970).

Predictability and state of the art and the Enablement Requirement (con't.)

- The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification.
- In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling.

-M.P.E.P. 2164.03

The Enablement Continuum

treatment cure prevention

Level or bar for enablement increases

Example A

- Claim 1. A chemical complex having Formula I.
- Claim 2. A pharmaceutical composition comprising the complex of claim 1 and a pharmaceutically acceptable carrier.
- Claim 3. A method of lowering the level of X in a cell or tissue, the method comprising contacting said cell or tissue with the complex of claim 1 in an amount sufficient to lower the level of X in said cell or tissue. (X is a type of oxygen radical)
- Claim 4. A method of treating or preventing a pathology by lowering the level of X in a subject by administering to said subject in need thereof a therapeutically effective amount of the complex of claim 1.
- Claim 5. The method of claim 4 wherein said pathology is selected from the group consisting of Alzheimer's disease, stroke, AIDS, dementia, autoimmune diseases, cancer, septic shock, chronic inflammation and atherosclerosis.

Example A: Facts

- The specification teaches how to make the complex having Formula I.
- The specification contains a single in vitro example in which cells in culture that have been exposed to the complex have lower levels of X relative to control cells.
- The specification does not establish a cause-effect relationship between the level of X and any disease, but teaches that the level of X is associated with pathologies enumerated in claim 5.

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Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

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Example A: Wands Analysis

- The nature of the invention is drawn to the treatment and prevention of pathologies through the administration of a chemical complex.
- The breadth of the claims is broad because it encompasses:
 - > both in vitro and in vivo contexts (claims 3-5)
 - > both treatment and prevention (claims 4-5)
 - > pathologies with vastly different etiologies or unknown etiologies (claim 5)
 - > pathologies beyond those in claim 5 (claim 4)

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Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
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Example A: Wands Analysis

- Look to the prior art for:
 - > teachings of similar complexes, their role in reducing levels of X and treatment or prevention of pathologies
 - > the etiologies of the claimed diseases, discern if they are shared or are divergent or even known
 - > information about the levels of X and association with pathologic conditions
 - > the level of X causing a disease or a symptom or is it a downstream effect?
 - > the ability to predict that an individual will develop one of the claimed diseases (Implications for preventative measures)

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Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the art
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

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Example A: Wands Analysis

- Look to the specification for:
 - > extension of knowledge of the prior art
 - > guidance to overcome challenges, obstacles, hurdles recognized in the art
 - > working examples: their absence is not fatal; however they are a form of teaching that could enable the skilled artisan to practice the claimed invention

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Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the art
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

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Example A: Wands Analysis

- The relative skill of those in chemical and biological arts is high.

Example A: Wands Analysis

- the nature of the invention
- the breadth of the claims
- the state of the prior art
- the predictability or lack thereof in the art
- the amount of direction or guidance present in the specification
- the presence or absence of working examples
- the relative skill of those in the art
- the quantity of experimentation needed

Example A: Wands Analysis

- The quantity of experimentation will be determined by how well the state of the prior art and its predictability mesh with the teachings of the disclosure.
- If these sources of knowledge available to a skilled artisan do not complement each other, then the skilled artisan must resort to empirical experimentation to practice the claimed invention, which could be undue (because of the factors discussed above).

Example A: Wands Analysis

- Consideration of all the evidence leads to a determination for enablement
- Possibilities for Example A, claims 3-5:
 - > Claim 3 may only be enabled for *in vitro* embodiments
 - > Claims 4-5 may only be enabled for treatment of only those diseases in which there is a cause/effect nexus between the levels of the disease and the disease (higher than mere association)
 - > Claims 4-5 may only be enabled for prevention of those diseases for which the skilled artisan can appropriately identify who will develop the disease in the future.

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